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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/868,026	01/11/2002	Jean-Luc Ridet	A3400PCT-US	5435

23117 7590 07/19/2004

NIXON & VANDERHYE, PC
1100 N GLEBE ROAD
8TH FLOOR
ARLINGTON, VA 22201-4714

EXAMINER

NICHOLS, CHRISTOPHER J

ART UNIT

PAPER NUMBER

1647

DATE MAILED: 07/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/868,026

Applicant(s)

RIDET ET AL.

Examiner

Christopher J Nichols, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 June 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 33-43 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 33-43 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 11 January 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 1 August 2002.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Request for Continued Examination

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 4 June 2004 has been entered.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Withdrawn Rejections And/Or Objections

3. The Rejection of claims 1, 2, 3, 4, 6, and 13 under 35 U.S.C. §102(b) as set forth at pp. 2-3 ¶4-7 in the previous Office Action (8 December 2003) is *moot* in view of Applicant's cancellation of said claims (4 June 2004).
4. The Rejection of claims 7-12 under 35 U.S.C. §102(b) as set forth at pp. 3-4 ¶8-11 in the previous Office Action (8 December 2003) is *moot* in view of Applicant's cancellation of said claims (4 June 2004).

Claim Objections

5. Claim 39 is objected to because of the following informalities: "and" is misspelled in the second line; "AAV" first recitation of acronym without definition. Appropriate correction is required.

Claim Rejections - 35 USC § 102

6. Claims 33-36 and 43 is rejected under 35 U.S.C. 102(b) as being anticipated by De Groot *et al.* (1997) “Establishment of Human Adult Astrocyte Cultures Derived from Postmortem Multiple Sclerosis and Control Brain and Spinal Cord Regions: Immunophenotypical and Functional Characterization” Journal of Neuroscience Research 49: 342-354 (IDS #BU).
7. The Examiner notes that claim 33 uses “comprising” which constitutes open claim language allowing for additional steps to be included. Only use of closed claim language “consisting of” will preclude art from being used which includes the claim steps as well as others not claimed [see MPEP §2111.03].
8. De Groot *et al.* (1997) teaches a method of isolating an essentially pure culture of astrocytes from “resected tissue samples from brain or spinal cord” of adult humans which were grown in 80 cm² flasks that were incubated for 48 hours at which time the “culture medium was changed to remove unattached cells and myelin debris” thus meeting the limitations of claims 33, 34, 35, and 36 (“**Astrocyte-Enriched Cell Cultures**” pp. 344). De Groot *et al.* (1997) also teaches that said method yielded a cell culture comprising 98% GFAP⁺ astrocytes and no microglia thus meeting the limitations of claims 33 and 43 (pp. 347).
9. Concerning any real or perceived differences between the method of preparation of claim 33 and De Groot *et al.* it has been established by the courts that a product inherently possesses characteristics of that product (i.e. including the amino acid sequence of a protein). See, e.g., *Ex parte Gray*, 10 USPQ 2d; *In re Best*, 195 USPQ 430). In addition,

“the PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his claimed product. Accordingly, since the

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issue in the present appeal is whether the prior art factor is identified or patently indistinct from that of the material on appeal, appellants have the burden of showing that inherency is not involved". *Ex parte Gray*, 10 USPQ 2d 1922 (1989); *In re Best*, 195 USPQ 430 (CCPA 1976).

Moreover, when the product in a product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior art product was made by a different process. *In re Thorpe*, 227 USPQ 964, 966 (Fed. Cir. 1985); *In re Marosi*, 218 USPQ 289, 292-293 (Fed. Cir. 1983). Lastly it is noted that the courts have held that when the prior art product reasonable appears to be the same as that claimed, but differs by process in which it is produced, a rejection of this nature is eminently fair and the burden is upon the appellants to prove, by comparative evidence, a patentable difference (*In re Brown*, 173 USPQ 685).

Claim Rejections - 35 USC § 103

10. Claims **33-42** are rejected under 35 U.S.C. 103(a) as being unpatentable over De Groot *et al.* (1997) "Establishment of Human Adult Astrocyte Cultures Derived from Postmortem Multiple Sclerosis and Control Brain and Spinal Cord Regions: Immunophenotypical and Functional Characterization" Journal of Neuroscience Research **49**: 342-354 (**IDS #BU**) in view of US 5,202,120 (13 April 1993) Silver *et al.* and US 5,650,148 (22 July 1997) Gage *et al.*

11. The Examiner notes that claim 33 uses "comprising" which constitutes open claim language allowing for additional steps to be included. Only use of closed claim language "consisting of" will preclude art from being used which includes the claim steps as well as others not claimed [see MPEP §2111.03].

12. De Groot *et al.* (1997) teaches a method of isolating an essentially pure culture of astrocytes from "resected tissue samples from brain or spinal cord" of adult humans which were

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grown in 80 cm² flasks that were incubated for 48 hours at which time the “culture medium was changed to remove unattached cells and myelin debris” thus meeting the limitations of claims 33, 34, 35, and 36 (“**Astrocyte-Enriched Cell Cultures**” pp. 344). De Groot *et al.* (1997) also teaches that said method yielded a cell culture comprising 98% GFAP⁺ astrocytes and no microglia thus meeting the limitations of claims 33 (pp. 347). However, De Groot *et al.* (1997) does not teach the transformation of said astrocytes with heterologous nucleic acids.

13. US 5202120 teaches that astrocytes may be immortalized by procedures such as a replication-defective RNA virus (retrovirus) for therapeutic use or to preserve the transfected astrocytes for future use thus meeting the limitations of claims 37-39 (Col. 13 lines 40-60).

14. US 5650148 teaches that primary astrocytes may be transfected with retroviral vectors containing transgenes such as growth factors, enzymes, gangliosides, neurotransmitters, neurohormones, toxins, neurite promoting molecules, antimetabolites (neuroactive substance) thus meeting the limitations of claims 37, 38, and 42 (Col. 7 lines 1-5; Col. 13 lines 1-12, 30-47; Col. 22 lines 7-16). US 5650148 teaches that primary astrocytes may be transfected with viral (DNA viruses) and retroviral (RNA viruses) vectors such as herpes virus, adenovirus, vaccinia, any of which may be defective viral vectors thus meeting the limitations of claims 38, 39, and 40 (Col. 14 lines 6-12; Col. 15 lines 35-40; Col. 16 lines 17-67; Col. 22 lines 7-16). US 5650148 teaches that primary astrocytes may be transfected with the above transgene using calcium phosphate transfection and cationic liposomal mediated transfection thus meeting the limitations of claims 37 and 41 (Col. 16 lines 60-67; Col. 22 lines 7-16; Claims 5-8, 15-18, and 25).

15. It would be obvious to a person of ordinary skill in the time of the invention to transfect the astrocyte cell line as taught by De Groot *et al.* (1997) with the heterologous nucleic acids as

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taught by US 5650148 using the viral vectors taught by US 5202120 and US 5650148 because it is advantages as therapeutics and can be maintained indefinitely (US 5650148 Col. 21-22; US 5202120 Col. 13 lines 40-60).

16. A person of ordinary skill in the art at the time of the invention would be motivated to make an astrocyte cell line using the methods taught by US 5650148 because US 5650148 teaches that astrocytes may be used in therapies (Col. 21-22).

17. A person of ordinary still in the at the time of the invention would have a reasonable expectation of success because US 5627047 clearly demonstrates the transfection of astrocytes with heterologous nucleic acids (claims 1-37).

18. Thus the invention as a whole was *prima facie* obvious over the prior art.

Summary

19. No claims are allowed.

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Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Christopher James Nichols, Ph.D.** whose telephone number is **(571) 272-0889**. The examiner can normally be reached on Monday through Friday, 8:00 AM to 6:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Brenda Brumback** can be reached on **(571) 272-0961**.

The fax number for the organization where this application or proceeding is assigned is **703-872-9306**.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at **866-217-9197** (toll-free).

CJN
July 2, 2004


BRENDA BRUMBACK
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600